Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0887993	(X3) Date Survey Completed 12/10/2021
Name of Provider or Supplier Las Vegas Urology-Smoke Ranch	**Street Address, City, State** 7500 Smoke Ranch Road Suit 200, Las Vegas, NV	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	This Statement of Deficiencies was generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on 12/10/2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Reports 153D and 155D, American Proficiency Institute (API) proficiency testing (PT) evaluation forms, and

	interview with the Director of Laboratory Compliance on 12/10/2021, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two consecutive testing events for the second and third testing events of 2021 with a score of 63% and 70%, respectively, resulted in unsuccessful proficiency testing performance for the subspecialty of bacteriology. Findings include: The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for the subspecialty of bacteriology in the second and third testing events of 2021. Refer to D2028.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Reports 153D and 155D, American Proficiency Institute (API) proficiency testing (PT) evaluation forms, and interview with the Director of Laboratory Compliance on 12/10/2021, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two consecutive testing events for the second and third testing events of 2021 with a score of 63% and 70%, respectively, resulted in unsuccessful proficiency testing performance for the subspecialty of bacteriology. Findings include: 1. The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for the subspecialty of bacteriology in the second and third testing events of 2021 with scores of 63% and 70%, respectively. 2. CASPER Reports 153D and 155D and the API PT Performance Evaluation reported scores of 63% and 70% for bacteriology for the second and third testing events, respectively, of 2021. 3. The Director of Laboratory Compliance interviewed on 12/10/2021 at approximately 8:30 AM confirmed the findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Reports 153D and 155D, American Proficiency Institute (API) proficiency testing (PT) evaluation forms, and interview with the Director of Laboratory Compliance on 12/10/2021, the Condition: Laboratories Performing High Complexity Testing; Laboratory Director was not met. The labortory director, high complxity testing, failed to provide overall management and direction in accordance with CFR 493.1445 of this subpart. Findings include: The laboratory director failed to ensure tht the laboratory successfully participated in a PT

	program, approved by CMS; as descirbed in subpart 1 of this part for each specialty, subspeicalty, and analyte or test in which the laboratory is certifed under CLIA. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Reports 153D and 155D, American Proficiency Institute (API) proficiency testing (PT) evaluation forms, and interview with the Director of Laboratory Compliance on 12/10/2021, the laboratory did not successfully participate in a proficiency testing program. The laboratory director failed to ensure that proficiency testing samples were tested as required. Findings include: 1. The laboratory failed to achieve an overall satisfactory proficiency testing event performance for two consecutive testing events for the second and third testing event of 2021 with score of 63 % and 70%, respectively, in the subspecialty of bacteriology which resulted in unsuccessful proficiency testing performance. 2. CASPER Reports 153D and 155D and API PT Performance Evaluations reported scores of 63% and 70% for the second and third testing events, respectively, of 2021 in bacteriology. 3. In a telephone interview on 12/10/2021 at approximately 8:30 AM, the Director of Laboratory Compliance confirmed the laboratory's unsuccessful performance in two consecutive bacteriology testing events for 2021.